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Tab # 7 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: _K133028_

7.1 Date of Submission

09/15/2013

7.2 Sponsor

Synaptic Medical Limited

Building C, 100 Kechuang 6th Street
Beijing Economic-Technological Development Area
Beijing, 100176, PR China

Establishment Registration Number: Not yet registered

Contact Person: Mr. Yang, Tiecheng
Position: Quality Director
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7.3 Submission Correspondent

Ms. Diana Hong & Mr. Tarzan Wang

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 240-238-7587
Email: info@mid-link.net

7.4 Identification of Proposed Device

Trade Name: Rithm ID™ Electrophysiology Catheter
Common Name: Electrophysiology Catheter

Regulatory Information:
Classification Name: Catheter, Electrode Recording
Classification: II;
Product Code: DRF;
Regulation Number: 21 CFR 870.1220;
Review Panel: Cardiovascular;

Intended Use Statement:

The Rithm ID™ Electrophysiology Catheter can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

7.5 Device Description

The Rithm ID™ Electrophysiology Catheters have been designed to facilitate electrophysiological mapping of cardiac structures in 115 models and 17 kind of curves.

The catheter has a high-torque shaft with an array of platinum electrodes at the distal tip that can be used for recording.The high-torque shaft allows the plane of the distal curve to be manually rotated to assist in positioning the catheter tip at the desired site.

The Rithm ID™ Electrophysiology Catheters have to connect with the EP by interface cables, model C18RS04S, C25S04S, C18RS10S and C25RS10S with different trunk length, leadwire and equipment connector for the different Electrophysiology Catheters.

7.6 Identification of Predicate Device

510(k) Number: K002976
Product Name: Diagnostic Electrophysiology Catheter
Manufacturer: St. Jude Medical,DAIG Division

7.7 Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1:2005 Medical Electrical Equipment-Part 1 General Requirements for basic safety and essential performance;
- IEC 60601-1-2:2007 Medical Electrical Equipment - Part 1-2 General Requirements for basic safety and essential performance - collateral standard: Electromagnetic compatibility - Requirements and tests;
- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity;
- ISO 10993-11:2006 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity;
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization;
- ISO 10993-4:2002 Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood;
- ASTM F88/F88M-09, Standard Test Method for Seal Strength of Flexible Barrier Materials;
- ASTM F1140-07 (Reapproved 2012), Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages;
- Bench Test 1: Surface, Dimensions and Shape Keeping of Tip Curve;
- Bench Test 2: Buckling Force, Tip Fatigue, Shaft Fatigue, Torsional Strength, Tensile Strength, Connector Retention Force;
- Bench Test 3: Electrode Isolation, Electrode Conductor Resistance, Insulation Resistance;
- Bench Test 4: Corrosion Resistance and Radio-detectability;
- Bench Test 5: Freedom from leakage;
- Bench Test 6: Shape Keeping of Tip Curve, Electrode Conductor Resistance on Simulation Test;
- Bench Test 7: Acquiring Clear Intracardiac Electrograms Test;
- Bench Test 8: Stimulating Capability Test.

7.8 Clinical Test Conclusion

No clinical study is included in this submission.

7.9 Substantially Equivalent (SE) Comparison

Table 6-1 Comparison of Technology Characteristics

ITEM	**Proposed Device** Rithm ID™ Electrophysiology Catheter	**Predicate Device** Diagnostic Electrophysiology Catheter K002976	Remark
Product Code	DRF	DRF	SE
Regulation No.	21 CFR 870.1220	21 CFR 870.1220	SE
Class	Class II	Class II	SE

Intended Use	The Rithm ID™ Electrophysiology Catheter can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.	Daig Electrophysiology Catheters can be used in the evaluation of a variety of cardiac arrhythmias form endocardial and intravascular sites.	SE
Configuration	Cable Connector	Cable Connector	SE
	Tip Electrode	Tip Electrode	SE
	Shaft	High-torque shaft	SE
	Strain reinforcement shrink tubing	Strain reinforcement shrink tubing	SE
Features	Fixed Curve	Fixed Curve	SE
	High-torque shaft	High-torque shaft	SE
	Electrode Spacing	Electrode Spacing	SE
	Multiple curve and length option	Multiple curve and length option	SE
How Supplied	EO Sterilized	EO Sterilized	SE

7.10 Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 4, 2014

Synaptic Medical Limited
c/o Diana Hong
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 CH

Re: K133028
Trade/Device Name: Rithm ID Electrophysiology Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode recording catheter or electrode recording probe
Regulatory Class: Class II
Product Code: DRF
Dated: January 26, 2014
Received: January 30, 2014

Dear Ms. Hong,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Tab # 6 Indications for Use Statement

510(k) Number: K133028

Device Name: Rithm ID™ Electrophysiology Catheter

Indications for Use:

The Rithm ID™ Electrophysiology Catheter can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

☒ PRESCRIPTION USE (Part 21 CFR 801 Subpart D)	OR	☐ OVER-THE-COUNTER USE (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Linda J. Ricci -S
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